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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,146	08/10/2000	Mark Chasin	332.1106	6582

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	11

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/636,146	Applicant(s) CHASIN ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a composition, classified in class 424, subclass 400+.

II. Claims 6-10, drawn to a method of treating a mammal suffering from a disease state, classified in class 514, subclass 262, 221, 231.2, 211.01, 222.2, and 212.01.

III. Claims 11-15, drawn to a compounds, classified in class 544, subclass 265.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating a mammal suffering from a disease such as asthma can be treated with a materially different composition such as albuterol.

Inventions III and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating a mammal suffering from a disease such as allergies can be treated with a materially different composition such as loratadine.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group I functions as a pharmaceutical composition. It has a utility purpose of treating or preventing a disease or disorder. The invention of Group III functions as chemical compounds which is considered as a different status of art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

Claims 1-10 are generic to a plurality of disclosed patentably distinct species comprising an active agent which is represented by compound of Formula recited in claim 1.

Some of these include, for example, when R_6 is O, R_3 and R_8 are methyl, it is classified in class 514, subclass 262;

when R_6 is O, R_3 and R_8 are Q, and Z is NH_2, A and B forms a seven-member ring, it is classified in class 514, subclass 221;

when R_6 is O, R_3 and R_8 are K, and W is a morpholinyl group, it is classified in class 514, subclass 231.2;

when R_6 is O, R_3 and R_8 are K, and W is a thiaoxazyl group, it is classified in class 514, subclass 211.02;

when R_6 is O, R_3 and R_8 are K, and W is a azaprine group, it is classified in class 514, subclass 212.01;

when R_6 is O, R_3 and R_8 are K, and W is a thiazaprine group, it is classified in class 514, subclass 222.02;

Due to the structural dissimilarities of active compounds encompassed by the claims and their corresponding diversity in classification, the search for all species presents an undue burden on the office.

Moreover, claims 6-10 are generic to a plurality of disclosed patentably distinct species comprising a disease states associated with abnormally high physiologic level of cytokine. The species are, for example, asthma, allergies, inflammation, depression, and dementia. The method of treating each of these disease states are patentably distinct from each other because these disease states are routinely treated with different modalities and/or agents, which they cannot be used interchangeably. For example, depression is routinely treated with tricyclic antidepressants, which are not useful for treating asthma or dementia or inflammation; asthma is routinely treated with β_2-

agonists, which are not useful treating allergies or depression; allergies are routinely treated with histamine blockers, which are not useful in treating depression or inflammation or dementia.

Due to the different distinct disease states encompassed by the claims and the different medical technologies associated thereto, the search for all species presents an undue burden on the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed active agent compound if the invention of Group I is elected, even though this requirement is traversed. In addition, Applicant is required under 35 U.S.C. 121 to elect a single disclosed active agent compound **and** a single disclosed disorder if the invention of Group II is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
December 17, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600